

REMARKS

Claims 1, 5, 6, 16, 20 and 21 are all the claims pending in the application.

Claims 1, 5, 6, 16, 20 and 21 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Brantman (US 4,687,782) in view of Soop *et al.* (1988 J Appl Physiol 64(6): 2394-2399).

This rejection should be withdrawn because Brantman and Soop *et al.* do not disclose or render obvious the present invention, either alone or in combination.

In the Response under 37 C.F.R. § 1.111 filed March 10, 2010, Applicants argued that (i) Soop *et al.* is not sufficient to provide motivation to one skilled in the art to omit carnitine from the composition of Brantman; and Brantman employs carnitine with other specific amino acids to promote muscle adaptation to strenuous exercise; (ii) omission of carnitine from the composition of Brantman would render it unsatisfactory for its intended purpose; relevant law holds that if a proposed modification would render a prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification; and the claimed composition retains and improves the desired function even carnitine, which was an essential element of Brantman's composition, is omitted

In the Office Action, the Examiner states (1) and (2) below in response to the Applicant's arguments (i) and (ii), respectively.

(1) It should be noted that MPEP 2144.02 states that the omission of an element and its function is obvious if the function of the element is not desired, citing *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989).

(2) Since Soop *et al.* disclose that adequate muscle carnitine levels are maintained during exercise, then there would still be appropriate level of carnitine present in the body when said

composition is administered during exercise, so that the branched amino acids will be oxidized and toxic ammonia will be removed. Therefore, it would be reasonable for one of ordinary skill to want to exclude carnitine from said composition of Brantman since the function of said carnitine is not desired and said composition of Brantman would still have the same intended purpose without carnitine being present.

However, Applicants disagree with the Examiner's position in the points of view described below.

First, the legal precedent cited by the Examiner does not apply to the present case.

In the present case, Brantman clearly teaches, at col. 4, lines 8-12, that "the present invention employs carnitine to optimize skeletal muscle function in relation to oxidation of fatty acids for calories; to the oxidation of BAA for the effects summarized above; and to enhance the removal of toxic ammonia."

Further, Brantman expressly discloses that the intended purpose of the composition is to provide "a dietary supplement which provides the best metabolic milieu to permit and encourage protein synthesis in skeletal muscle and in liver ... [and that] the objects of the invention are realized by a careful selection of specific amino acids to be added to whole protein and other nutrients, so as to achieve a diet which is enriched with specific amino acids (carnitine, glutamine, isoleucine, leucine and valine), in order to maximize protein synthesis in skeletal muscle" (col. 4, lines 18-30).

That is, contrary to the Examiner's characterization that carnitine is not a desired component in the composition of Brantman, Brantman specifically requires the use of carnitine for its intended purpose.

Second, although Soop *et al.* teaches that adequate muscle carnitine levels are maintained during exercise and that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions, Soop *et al.*'s study relates to the single use of carnitine and its effect on skeletal muscle metabolism under normal physiological conditions.

That is, the level of carnitine taught by Soop *et al.* might not be adequate for the purpose taught by Brantman (optimize skeletal muscle function, provides the best metabolic milieu, and maximize protein synthesis in skeletal muscle). Further, Brantman employs carnitine with other specific amino acids to promote muscle adaptation to strenuous exercise.

Third, the composition defined in the claims of the instant application is patentable over Brantman from the fact that the claimed composition retains and improves the desired function even carnitine, which was an essential element of Brantman's composition, is omitted. The omission of an element and retention of its function is an indicia of unobviousness. In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966); MPEP 2144.04.

Furthermore, the Examiner asserts that one of ordinary skill in the art know that excluding carnitine from said composition of Brantman would be cost effective at page 7, lines 5-6 of the Office Action.

However, one of ordinary skill in the art would recognize that according to Brantman, omission or exclusion of carnitine would markedly reduce desired physiological effects of the composition. Accordingly, one of ordinary skill in the art would not have prioritized the cost reduction effects at the cost of such physiological effects. Furthermore, since carnitine is only one component among the total six components, large cost reduction effects cannot be expected even if carnitine is excluded. Therefore, one of ordinary skill in the art would not have been motivated to exclude carnitine which is taught as an essential component, from the composition

of Brantman. The priority for such slight cost reduction effects would be much lower than that for maintaining the physiological effects.

In view of the above, the present claims are not obvious and are patentable over Brantman and Soop *et al.*, either alone or in combination. Reconsideration and withdrawal of the §103(a) rejection based on Brantman in view of Soop *et al.* are respectfully requested.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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